EPA 600/R-05/015

Draft Timeline
Prepare to Implement a Cohort Study of Children's Environmental Health

Prepared for:

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Disclaimer:

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First Deliverable: Draft Timeline

Prepare to Implement a Cohort Study of Children's Environmental Health

Work Assignment Number: 02-10

RTI Project No. 08601.001.010

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1.0 Overview of Schedule for EPA WA 02-10, 68-D-02-069: Prepare to Implement a Cohort Study of Children's Environmental Health

The National Children's Study (NCS) is a 20-year prospective cohort study, which will investigate the causal relationships between environmental, physical, and sociocultural exposures with prenatal and childhood development. Since 2000, the National Institute of Child Health and Human Development (NICHD), the U.S. EPA, CDC, and NIEHS have undertaken planning, design, and pilot testing of the National Children's Study (NCS) to ensure that the NCS meets the highest scientific standards.

To transition the NCS from the planning to the implementation phases of the study, U.S. EPA issued this work assignment to RTI to provide strategic recommendations for successful implementation of a demonstration, or pre-vanguard, cohort in North Carolina. This deliverable was prepared under Task 5 of the work assignment and consists of a timeline for study implementation. While the schedule conveys our best understanding of the work required to initiate the study of the NC Cohort, it is important to note that the schedule may change as the NCS is further planned, and as we come to closure on sampling strategy.

2.0 Tasks and Assumptions

Our draft study timeline (included as Attachment A) categorizes the NC Cohort into 8 major task areas. These tasks along with accompanying assumptions are described as follows:

. • ***Task 1: Protocol Development***. During this period, we expect to work closely with U.S. EPA to define the assessments and questionnaires to be used, as well as the biospecimen collection methods and environmental sampling methods. We are assuming that we will receive finalized assessments on a flow-basis from U.S. EPA with the last of the assessments arriving by 12/21/04. The remainder of the schedule is based on the critical assumption that all assessments, questionnaires, biospecimen collection methods, and environmental sampling methods will be finalized by 12/21/04.

. • ***Task 2: Clearances.*** We are assuming three separate and sequential IRB clearance processes: for EPA, for RTI, and for clinical sites (i.e., prenatal health care providers). We expect that the OMB approval process will take approximately 6 months, beginning with the Federal Register Notice submission on 3/11/05.

. • ***Task 3: Sampling Strategy.*** For sampling, we will purposively identify two test areas (one urban, one rural) to serve as nominal PSUs. These nominal PSUs will be identified so as to be typical of the PSUs we would expect in the full NCS. Possible areas include Wake County and Johnson County North Carolina. We are contemplating both an area frame sample and a clinical sample in order to obtain the 25% of the sample allocation of women of child-bearing age who are currently not pregnant. Probability-based sampling will occur from a list sample of clinical sites (i.e., prenatal health care providers) to improve the efficiency of the sample for obtaining the remaining 75% of the sample. The methodology task for sampling women of childbearing age who are currently not pregnant and women in their first trimester of pregnancy will include both the area frame methodology and the list sample methodology.

- ***Task 4: Materials Development***. We are assuming that development of MOPs, QAPPs, and SOPs can occur concurrently. Materials development will depend on finalization of the assessments in Task 1. As seen from the schedule, materials development will also include ample time for finalization, including time for the U.S. EPA to review and provide feedback on the materials, as well as time for RTI to incorporate feedback on the materials.
- ***Task 5: Systems Development***. Because the NCS will draw upon the latest technologies available for data collection, we are assuming that data collection will include computer-assisted interviewing (CAI) technology, which will require corresponding programming. Similarly, case management systems, biospecimen tracking systems, and information systems at clinical sites will all require programming and testing time.
- ***Task 6: Community Outreach***. Involving community partners (i.e., those organizations in the community with the ability, membership, motivation, and capacity to promote participation in the NCS among members) will be a critical part of the NCS and in this demonstration cohort. This schedule allows for community partner participation in the materials development task, as well as their involvement in developing and disseminating outreach materials to promote the study and maintain the cohort.
- ***Task 7: Biospecimen and Environmental Sampling Preparation.*** Due to the complexity of biological and environmental data required for analysis, we have allocated Task 7 to identify, order, receive, and inventory supplies and equipment needed to collect biological and environmental samples among cohort members.
- ***Task 8: Training.*** We define training as training data collection staff in the study protocol and data collection processes. Subtasks include developing and finalizing a training plan, training schedule, training materials, and conducting the training. While we have placed the training as close to the data collection as possible, there is room in the schedule to extend the time for training to an earlier date.

3.0 Key Milestones

Completion dates for the eight tasks and key subtasks or milestones are listed below:

- Task 1: 2/15/05
- Task 2: 12/2/05

EPA Submits Federal Register Notice: 3/11/05
Submit Final OMB Package: 7/20/05
OMB Approval Received: 10/27/05

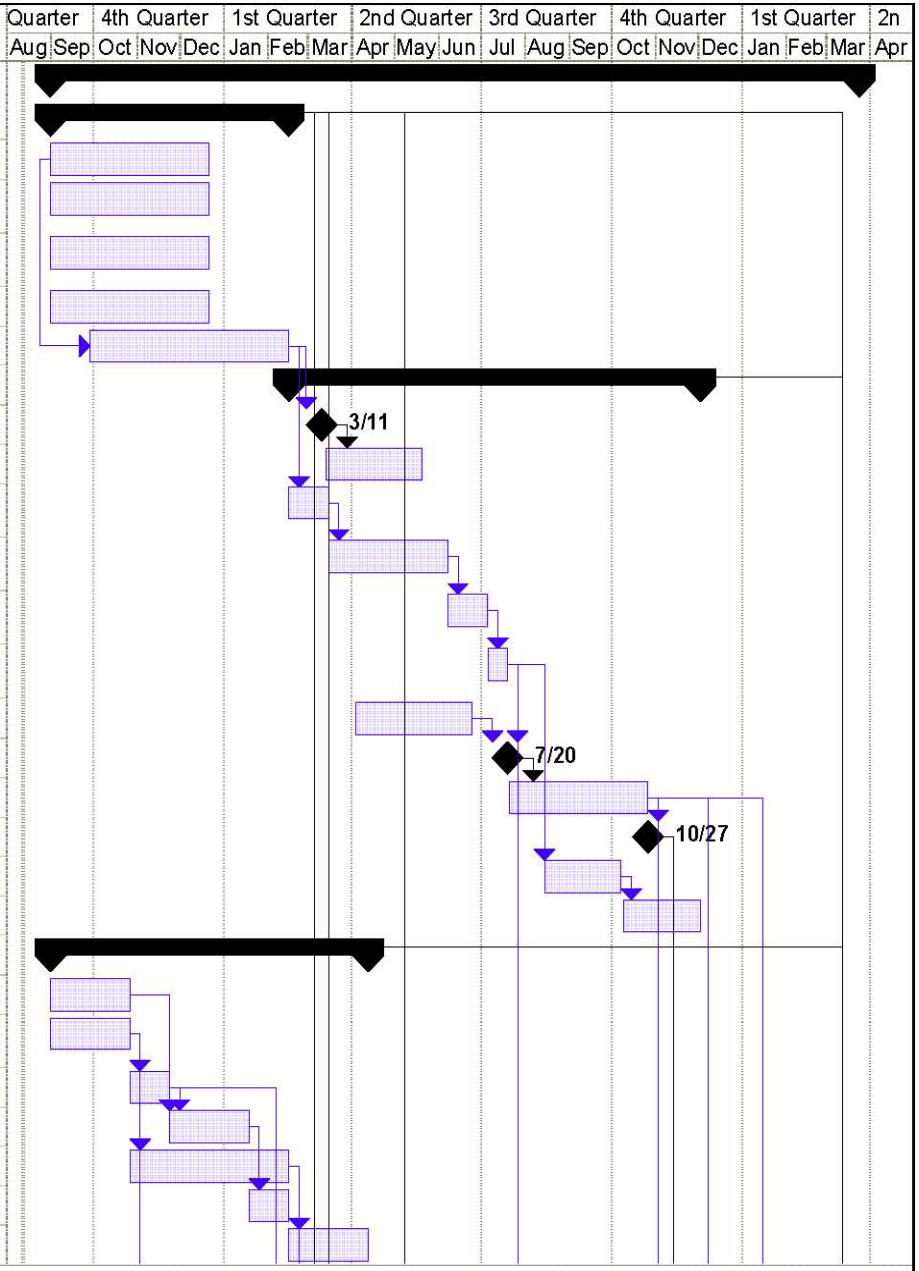
- Task 3: 4/12/05
- Task 4: 1/19/06

Submit Draft MOPs, QAPPs, SOPs: 5/11/05
Submit Final MOPs, QAPPs, SOPs: 11/24/05

- Task 5: 1/3/06
- Task 6: 2/15/06
- Task 7: 11/25/05
- Task 8: 3/24/06

Attachment A

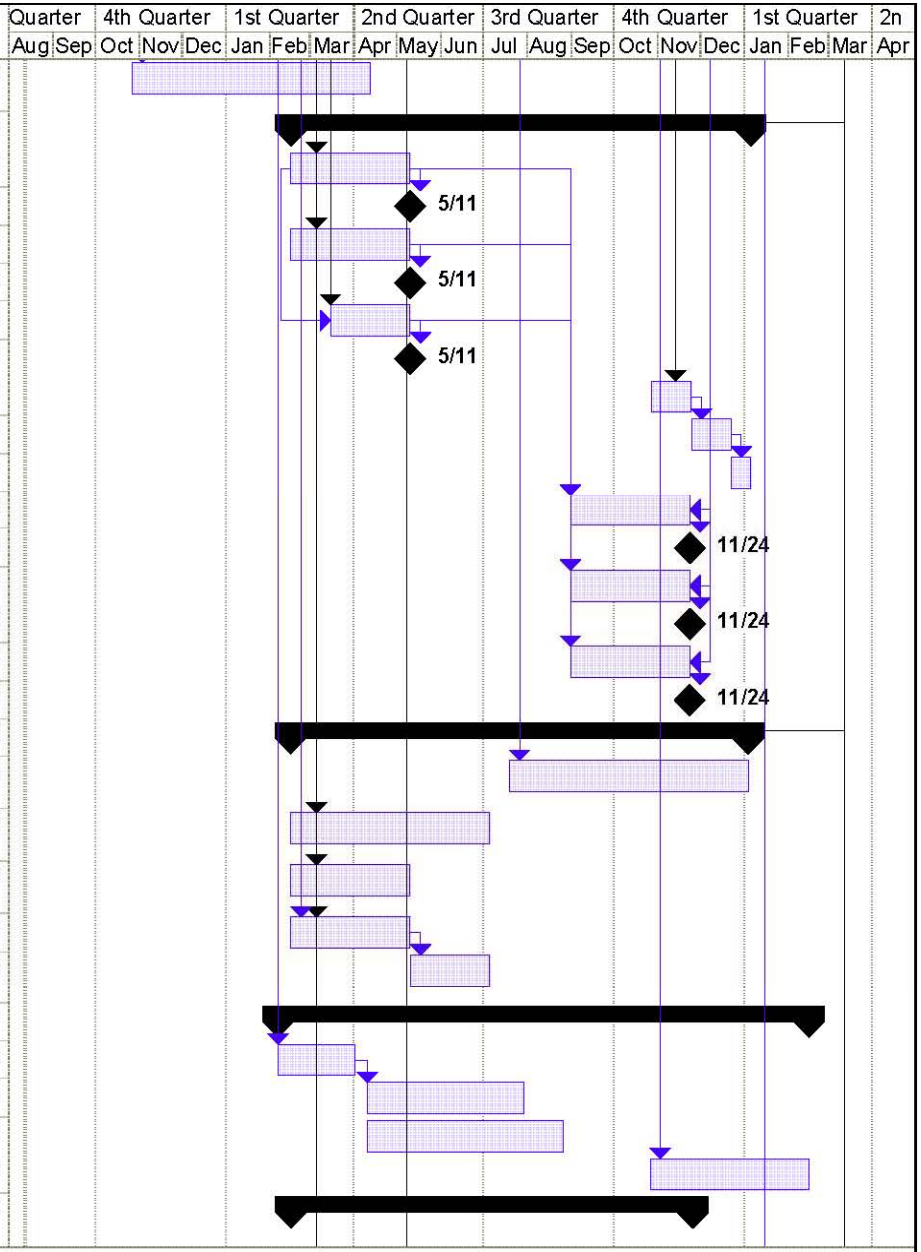
ID	Task Name	Duration	Start	Finish
1	**Start up to Data Collection**	**408 days**	**Wed 9/1/04**	**Fri 3/24/06**
2	**Task 1: Protocol Development**	**120 days**	**Wed 9/1/04**	**Tue 2/15/05**
3	Finalize Assessments from EPA	4 mons	Wed 9/1/04	Tue 12/21/04
4	Finalize Biospecimen Collection Methods	4 mons	Wed 9/1/04	Tue 12/21/04
5	Finalize Environmental Sampling Methods	4 mons	Wed 9/1/04	Tue 12/21/04
6	Finalize Questionnaire	4 mons	Wed 9/1/04	Tue 12/21/04
7	Finalize Study Protocol	5 mons	Wed 9/29/04	Tue 2/15/05
8	**Task 2: Clearances**	**208 days**	**Wed 2/16/05**	**Fri 12/2/05**
9	EPA Submits Federal Register Notice	1 day	Fri 3/11/05	Fri 3/11/05
10	OMB Federal Register Notice period	2.5 mons	Mon 3/14/05	Fri 5/20/05
11	Prepare EPA Human Subjects IRB Package	1 mon	Wed 2/16/05	Tue 3/15/05
12	Obtain EPA Human Subjects IRB Approval	3 mons	Wed 3/16/05	Tue 6/7/05
13	Prepare RTI Human Subjects IRB Package	1 mon	Wed 6/8/05	Tue 7/5/05
14	Obtain RTI Human Subjects IRB Approval	2 wks	Wed 7/6/05	Tue 7/19/05
15	Prepare OMB Package	3 mons	Mon 4/4/05	Fri 6/24/05
16	Submit Final OMB Package	1 day	Wed 7/20/05	Wed 7/20/05
17	Obtain OMB Approval	3.5 mons	Thu 7/21/05	Wed 10/26/05
18	OMB Approval Received	1 day	Thu 10/27/05	Thu 10/27/05
19	Prepare Clinical Sites IRB Packages	2 mons	Mon 8/15/05	Fri 10/7/05
20	Obtain Clinical Sites IRB Approvals	2 mons	Mon 10/10/05	Fri 12/2/05
21	**Task 3: Sampling Strategy**	**160 days**	**Wed 9/1/04**	**Tue 4/12/05**
22	Finalize Sampling Strategy	2 mons	Wed 9/1/04	Tue 10/26/04
23	Finalize Sampling Strata and Sampling Rates	2 mons	Wed 9/1/04	Tue 10/26/04
24	Identify PSUs	1 mon	Wed 10/27/04	Tue 11/23/04
25	Select Area Segments	2 mons	Wed 11/24/04	Tue 1/18/05
26	Recruit Hospitals and Clinical Sites	4 mons	Wed 10/27/04	Tue 2/15/05
27	Obtain Segment Address Lists	1 mon	Wed 1/19/05	Tue 2/15/05
28	Recruit Physicians	2 mons	Wed 2/16/05	Tue 4/12/05



Project: NC Cohort Start-up Timeline
Date: Thu 8/12/04

Task
Split
Progress
Milestone
Summary
Project Summary
External Tasks
External Milestone
Deadline

ID	Task Name	Duration	Start	Finish
29	Develop Methodology for Sampling Women	6 mons	Wed 10/27/04	Tue 4/12/05
30	**Task 4: Materials Development**	**232 days**	**Wed 2/16/05**	**Thu 1/5/06**
31	Prepare MOPs	3 mons	Wed 2/16/05	Tue 5/10/05
32	Submit Draft MOPs	1 day	Wed 5/11/05	Wed 5/11/05
33	Prepare QAPPs	3 mons	Wed 2/16/05	Tue 5/10/05
34	Submit Draft QAPPs	1 day	Wed 5/11/05	Wed 5/11/05
35	Prepare SOPs	2 mons	Wed 3/16/05	Tue 5/10/05
36	Submit Draft SOPs	1 day	Wed 5/11/05	Wed 5/11/05
37	Finalize Materials	1 mon	Fri 10/28/05	Thu 11/24/05
38	Translate Materials	1 mon	Fri 11/25/05	Thu 12/22/05
39	Print Materials	2 wks	Fri 12/23/05	Thu 1/5/06
40	Finalize MOPs	3 mons	Thu 9/1/05	Wed 11/23/05
41	Submit Final MOPs	1 day	Thu 11/24/05	Thu 11/24/05
42	Finalize QAPPs	3 mons	Thu 9/1/05	Wed 11/23/05
43	Submit Final QAPPs	1 day	Thu 11/24/05	Thu 11/24/05
44	Finalize SOPs	3 mons	Thu 9/1/05	Wed 11/23/05
45	Submit Final SOPs	1 day	Thu 11/24/05	Thu 11/24/05
46	**Task 5: Systems Development**	**230 days**	**Wed 2/16/05**	**Tue 1/3/06**
47	Program/Test Data Collection Instruments	6 mons	Wed 7/20/05	Tue 1/3/06
48	Program/Test Case Management System	5 mons	Wed 2/16/05	Tue 7/5/05
49	Program/Test Biospecimen Tracking Systems	3 mons	Wed 2/16/05	Tue 5/10/05
50	Develop Clinical Site Systems	3 mons	Wed 2/16/05	Tue 5/10/05
51	Conduct Testing of Clinical Site Systems	2 mons	Wed 5/11/05	Tue 7/5/05
52	**Task 6: Community Outreach**	**268 days**	**Mon 2/7/05**	**Wed 2/15/06**
53	Identify Key Community Partners	2 mons	Mon 2/7/05	Fri 4/1/05
54	Recruit Community Partners	4 mons	Mon 4/11/05	Fri 7/29/05
55	Develop Outreach Materials	5 mons	Mon 4/11/05	Fri 8/26/05
56	Conduct Community Outreach	4 mons	Thu 10/27/05	Wed 2/15/06
57	**Task 7: Biospecimen Collection and Environmental Sampling Preparation**	**203 days**	**Wed 2/16/05**	**Fri 11/25/05**



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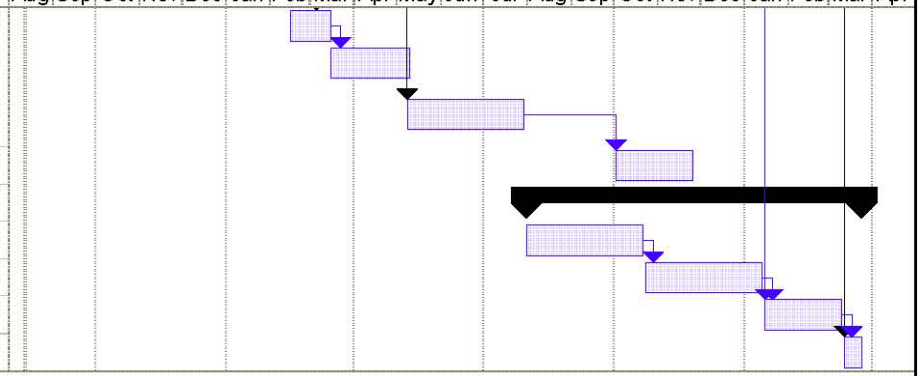
ID	Task Name	Duration	Start	Finish
58	Identify Lab Analyses Needed	1 mon	Wed 2/16/05	Tue 3/15/05
59	Establish Contracts with Laboratories	2 mons	Wed 3/16/05	Tue 5/10/05
60	Identify Supplies/Equipment Needed	3 mons	Mon 5/9/05	Fri 7/29/05
61	Order and Receive Supplies/Equipmen	2 mons	Mon 10/3/05	Fri 11/25/05
62	**Task 8: Training**	**170 days**	**Mon 8/1/05**	**Fri 3/24/06**
63	Develop Training Plan and Schedule	3 mons	Mon 8/1/05	Fri 10/21/05
64	Develop Training Materials	3 mons	Mon 10/24/05	Fri 1/13/06
65	Finalize Training Materials	2 mons	Mon 1/16/06	Fri 3/10/06
66	Conduct Training	2 wks	Mon 3/13/06	Fri 3/24/06



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